PRISMATIK
DENTALCRAFT, INC.

K133850

JUN 0 4 2014

005-510(k) Summary-807.92(c)

This 510(k) summary is being submitted in accordance with the requirements of SMDA and 21 CFR 807.92.

A. SUBMITTER INFORMATION

Company Name:	Prismatik Dentalcraft, Inc.
Company Address:	2212 Dupont Dr., Suite IJK, Irvine, CA 92612
Company Phone:	949-225-1269
Company FAX:	949-553-0924
Facility Registration Number:	3005477956
Primary Contact Person:	Armin Zehtabchi, (949) 225-1234 Senior RA
Secondary Contact Person	Marilyn Pourazar, (949) 225-1269 Senior Director, RA/QA
Date Summary Prepared:	June 3, 2014

B. DEVICE IDENTIFICATION

Trade/Proprietary Name:	Camouflage NanoHybrid Composite (Universal and Flowable)
21 CFR Reference:	21 CFR 872.3690
21 CFR Common Name:	Tooth shade resin material
Classification:	Class II
Product Code:	EBF
Panel:	Dental

C. IDENTIFICATION OF PREDICATE DEVICE

Trade/Proprietary Name: Composite 168 Restorative System (EsthetXHD/Flow) Dentsply-K973221

D. DEVICE DESCRIPTION

The Camouflage Nanohybrid Composite (Universal and Flowable) is a light cured resin-based composite restorative. It is offered in High Viscosity ("Camouflage Universal" paste) and Low Viscosity (Camouflage Flowable), and is recommended for direct and indirect placement in all caries classes (both anterior and posterior restorations, including occlusal surfaces). It is available in multiple shades and opacities, and is radio-opaque. It is composed of methacrylate monomers, Initiators, inhibitors, stabilizers, pigments, and inorganic fillers coated with a coupling agent. The Camouflage Nanohybrid Composite (Universal and Flowable) cures with light in the wavelength range of 400-500nm, and a dental adhesive is used to permanently bond the restoration to the tooth structure.

E. INDICATIONS FOR USE

The Camouflage NanoHybrid Composite (Universal and Flowable) are indicated for cavity classes I, II, III, IV, V, and VI in anterior and posterior teeth.

- May be used as a direct restorative material
- May be used for fabrication of inlays and onlays

F. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE PROPOSED DEVICE AND THE PREDICATE DEVICES

Prismatik utilized the **FDA's Guidance for Industry and FDA Staff - Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions** for comparing its Camouflage NanoHybrid Composite (Universal and Flowable) with the Composite 168 Restorative System (EsthetXHD/Flow) Dentsply-K973221. The following comparison table of the technological characteristics of the proposed device and the predicate device outlines and provides the similarities and the substantial equivalency of the Camouflage NanoHybrid Composite (Universal and Flowable) and the Composite 168 Restorative System (EsthetXHD/Flow) Dentsply-K973221.

Comparison of the Technological Characteristics of the Proposed and the Predicate Devices

	Predicate Device: Composite 168 Restorative System (EsthetXHD/Flow) Dentsply 510(k)-K973221	Proposed Device: Camouflage Nanohybrid Composite (Universal and Flowable)	Similarities and Difference Between the Predicate and the Subject Device
Classification of Polymer	Per ISO 4049 Type-1 Class-2 Group- 1&2 (Per ISO 4049)	Per ISO 4049 Type-1 Class-2 Group- 1&2 (Per ISO 4049)	Same
Intended Uses Per FDA Regulation	Intended to restore carious lesions or structural defects in teeth	Intended to restore carious lesions or structural defects in teeth	Same
Indications for use per 510k Clearance Letter	• Indicated for cavity classes I, II, III, IV, V, and VI in anterior and posterior teeth. • May be used as a direct restorative material • May be used for fabrication of inlays and onlays	• Indicated for cavity classes I, II, III, IV, V, and VI in anterior and posterior teeth. • May be used as a direct restorative material • May be used for fabrication of inlays and onlays	Same
FDA Description and Product Code Information	EBF 21 CFR 872.3690 Tooth shade resin material	EBF 21 CFR 872.3690 Tooth shade resin material	Same
General Material	Tooth shade resin material	Tooth shade resin material	Same
Delivery Method(s)	• Syringes	• Syringes	Same
	• Capsules Tips	• Capsules Tips	Same
Biocompatibility	Biocompatible	Biocompatible	Same
Sterility	Non-Sterile	Non-Sterile	Same
Single or Multiple Use	Single Patient, multiple use	Single Patient, multiple use	Same
Prescription/OCT Use	Prescription	Prescription	Same

G. DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The above comparison table of the technological characteristics of the proposed device and the predicate devices was provided for the substantial equivalency of the Camouflage NanoHybrid Composite (Universal and Flowable) and the Composite 168 Restorative System (EsthetXHD/Flow) Dentsply-K973221. Prismatik believes that the comparative

data presented, demonstrate that the Camouflage NanoHybrid Composite (Universal and Flowable) is essentially the same as currently marketed devices for the same indications for use, and supports our claim of substantial equivalence to predicate Class II devices under the classification of 21 CFR 872.3690 that have previously been found to be substantially equivalent. Both the proposed and the predicate device consist of the same Product Code: EBF, which is biocompatible for the same indications for use.

H. SUMMARY OF NON-CLINICAL TESTING

Non-clinical test data was used to support the substantial equivalency. Specifically, the Camouflage Nanohybrid Composite (Universal and Flowable) was evaluated using the relevant FDA recognized standard: **ISO 4049: 2009 Dentistry — Polymer-based restorative materials**. In addition, Prismatik utilized the **FDA's Guidance for Industry and FDA Staff - Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions**. To provide evidence, assurance for the device safety and meeting the **ISO 4049** requirements, Prismatik performed various testing including the Sensitivity to Ambient Light, Depth of Cure, Flexural Strength/Elastic Modulus, Water Absorption, Water Solubility, Shade Match/Shade Stability and Radio Opacity.

I. CONCLUSION FROM THE NON-CLINICAL TESTING

The results of the above described studies demonstrate that the Camouflage NanoHybrid Composite (Universal and Flowable) is substantially equivalent to the cleared predicate device, the Composite 168 Restorative System (EsthetXHD/Flow) Dentsply-K973221.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 4, 2014

Prismatik Dentalcraft, Inc.
C/O Mr. Armin Zehtabchi
Senior Regulatory Analyst
2212 Dupont Drive, Suite IJK
Irvine, CA 92612

Re: K133850
Trade/Device Name: Camouflage Nanohybrid Composite
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth shade, resin
Regulatory Class: II
Product Code: EBF
Dated: April 29, 2014
Received: April 30, 2014

Dear Mr. Zehtabchi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K133850

PRISMATIK
DENTALCRAFT, INC.

004-Indications for Use Statement

510(k) Number (if known): To be determined

Device Name: Camouflage NanoHybrid Composite (Universal and Flowable)

Indications for Use: The Camouflage NanoHybrid Composite (Universal and Flowable) are indicated for cavity classes I, II, III, IV, V, and VI in anterior and posterior teeth.
- May be used as a direct restorative material
- May be used for fabrication of inlays and onlays

Prescription Use: Yes ☒ No ☐
(Part 21 CFR 801 Subpart D)

Over-the-Counter Use: Yes ☐ No ☒
(Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
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